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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/056,058 | 01/28/2002 | Andrew William Heath | 010827.50861 | 5470 |

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| EXAMINER | |
|---|---|
| GAMBEL, PHILLIP | |
| ART UNIT | PAPER NUMBER |
| 1644 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 03/12/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/056,058 | HEATH, ANDREW WILLIAM | |
| | Examiner | Art Unit | |
| | Phillip Gambel | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *8/22/06; 12/5/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *5,10-16 and 20-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-9 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. As indicated previously, applicant's election with traverse of Group I and the species wherein the ligand is an anti-CD40 antibody in the Reply to Office Action, filed 8/22/06, is acknowledged. The traversal is on the ground(s) that the different classification, which was relied upon in the Restriction Requirement mailed 7/3/06, was not shown and, in turn, no adequate reason has been provided.

The indication of different classification between the Groups in the previous Restriction Requirement was an inadvertent error. The examiner apologizes for any misunderstanding or confusion to applicant in this matter. However, the following was also noted in the Restriction Requirement.

Inventions II I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the products as claimed can be used in a materially different process such as affinity purification procedures, bioassays or detection assays.

Alternatively, there are a number of adjuvant preparations that do not rely upon a CD40 ligand.

Further, the Restriction Requirement indicated that the Groups encompassed divergent subject matter as well.

For the reasons of record, applicant's arguments have not been found persuasive.

The Restriction Requirement is still deemed proper and is therefore made FINAL.

Applicant's election without traverse of the antigen species the T cell dependent influenza virus isolate A/Bangkok/10/83 in the Reply to Office Action, filed 12/5/06, is acknowledged.

Claims 1-29 are pending.

Claims 1-4, 6-9 and 17-19 are under consideration as they read on the elected invention and species.

Claims 5, 10-16 and 20-29 have been withdrawn as being withdrawn from consideration as being directed to a non-elected inventions and species.

2. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. **If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.**
See United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003).

Applicant should update the status of parent applications.

3. The filing date of the instant claims is deemed to be the filing date of instant application USSN 10/056,058, filed 1/28/02

Priority applications USSNs 09/938,477 and 08/878,348 do not support all of the current claim limitations, particularly "reducing the toxicity of an adjuvant to an animal", influenza antigen (versus Hemophilus influenza in the parent USSNs) and "influenza isolate A/Bangkok/10/83" of the instant application.

If applicant desires priority prior to 1/1/91; applicant is invited to point out and provide documentary support for the priority of the instant claims.
Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. 112, first paragraph.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

5. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required.

6. Claims 1-4, 6-9 and 17-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-4, 6-9 and 17-19 are indefinite in that "a CD40 ligand" (e.g., anti-CD40 antibody) should be the "adjuvant" according to the specification as filed as well as the election of species.

However, the recitation of the claims are not clear that the "CD40 ligand" (e.g., anti-CD40 antibody) is the adjuvant per se. Also, there is some ambiguity about proper antecedent basis since the preamble recites "an adjuvant", while the body of the claim recites "adjuvant preparation".

Applicant is invited to amend the claims to clarify that the CD40 ligand / anti-CD40 antibody is the adjuvant.

B) Claims 1-4, 6-9 and 17-19 are indefinite in the recitation of "a CD40 ligand", since CD40 ligand was at the time the application was filed and currently the designation for "the CD40 ligand", namely "CD154", and not a generic term to mean any molecule that binds CD40 as currently used in the instant claims.

Applicant is invited to amend the claims to replace a "CD40 ligand" with "anti-CD40 antibody" as the elected species (and, "CD40 ligand" as the non-elected species, if applicant desires) to avoid confusion as to the metes and bounds of "a CD40 ligand" to apprise one of ordinary skill in the art the metes and bounds of the claimed invention.

C) Claims 18-19 are indefinite in the recitation of "influenza isolate A/Bangkok/10/83" because its characteristics are not known. The use of "influenza isolate A/Bangkok/10/83" as the sole means of identifying the claimed influenza isolate renders the claim indefinite because "influenza isolate A/Bangkok/10/83" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designations to define completely distinct biological materials.

D) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(l).
Correction of the following is required:

The specification as-filed does not appear to provide sufficient written description for influenza isolate A/Bangkok/10/83.

Alternatively, applicant is invited to identify the written support for influenza isolate A/Bangkok/10/83 in the specification as filed (and as well as any USSN document relied upon for priority).

9. Claims 18-19 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the influenza isolate A/Bangkok/10/83 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate biological material provides for the influenza isolate A/Bangkok/10/83. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-4, 6-9 and 17 are rejected under 35 U.S.C § 102(b) as being anticipated by Heath (CA 2,207,246) (see entire document).

Heath teaches the use of anti-CD40 antibodies, including monoclonal and humanized antibodies and binding fragments thereof (e.g. see page 7, paragraphs 3-4; page 9, paragraphs 3-4; page 12, paragraphs 3-4) ) as adjuvants in the construction of vaccines to T-dependent antigens (e.g., see page 5, paragraph 1; page 6, paragraph 1; page 8, paragraph 4; page 9, paragraphs 6-7; page 10, paragraph 1), including Haemophilus influenzae (e.g. see page 18, Results and Discussion); including recombinant, co-joined and cross-linked formulations (e.g., see pages 5-12, including page 9, paragraph 7; page 10, paragraphs 2-5; page 12, paragraph 1; pages 22-23, overlapping paragraph).

With respect to the recitation of "reducing toxicity of an adjuvant", products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

The burden is on the applicant to establish a patentable distinction between the claimed and referenced methods of administering vaccines comprising anti-CD40 antibodies.

13. Claims 1-4, 6-9 and 17-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Heath (CA 2,207,246) in view of Okuno et al. (U.S. Patent No. 5,631,350)

Heath teaches the use of anti-CD40 antibodies, including monoclonal and humanized antibodies and binding fragments thereof (e.g. see page 7, paragraphs 3-4; page 9, paragraphs 3-4; page 12, paragraphs 3-4) as adjuvants in the construction of vaccines to T-dependent antigens (e.g., see page 5, paragraph 1; page 6, paragraph 1; page 8, paragraph 4; page 9, paragraphs 6-7; page 10, paragraph 1), including Haemophilus influenzae (e.g. see page 18, Results and Discussion); including recombinant, co-joined and cross-linked formulations (e.g., see pages 5-12, including page 9, paragraph 7; page 10, paragraphs 2-5; page 12, paragraph 1; pages 22-23, overlapping paragraph).

With respect to the recitation of "reducing toxicity of an adjuvant", products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

Heath differs from the claimed methods by not disclosing the particular virus strain A/Bangkok/10/83 as the influenza viral target of interest for the claimed methods of provoking an immune response.

Okuno et al. teach the known target of influenza viruses in the treatment and prevention of influenza, including the generation of antibodies thereto (see entire document, including Summary of the Invention). Among the targeted influenza viruses, Okuno et al. teach the particular virus strain A/Bangkok/10/83 (e.g., see Example 1 on columns 12-13; Example 3 on columns 14-16; Table 1 on column 16; Example 4 on columns 16-19; column 22, Properties of Monoclonal Antibody).

Given the prior art teachings of the applicability of anti-CD40 antibody based adjuvant – vaccine constructs to induce immune response to T cell dependent antigens such as viral antigens, including influenza as taught by Heath, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the particular virus strain A/Bangkok/10/83 into such constructs to generate immune responses to influenza viruses of interest such as particular virus strain A/Bangkok/10/83 in the treatment of influenza infections at the time the invention was made. Similarly, one of ordinary skill in the art would have been motivated to substitute the particular virus strain A/Bangkok/10/83 into the constructs taught by Heath, given the efficacy of the anti-CD40 adjuvant-vaccine constructs taught by Heath. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 5, 2007